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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/878,136	Ali et al.
Examiner	**Art Unit**
Michael C. Wilson	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Nov 5, 2002 .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-12 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☒ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The amendment filed 11-05-02, paper number 7, has been entered. Claims 9-12 have been added. Claims 1-12 are pending.

Election/Restriction

1. Applicant's election with traverse of Group II, claims 1-5, 7 and 8, in Paper No. 7, is acknowledged. The traversal is on the ground(s) that the burden required to search *in vivo* and *ex vivo* means of delivery of HSV-GM-CSF together is not undue. This is found persuasive.

Applicant's election with traverse of a herpes virus encoding GM-CSF in Paper No. 7 is acknowledged. Applicants state that upon allowance of a generic claim, the Applicants are entitled to consideration of claims to additional species. It is noted, however, that all of the originally filed claims are generic to any "cell-damaging agent" which encompasses patentably distinct species which have not been claimed.

Applicants have not stated which claims are generic to the elected invention which is considered non-responsive. However, as a means of expediting prosecution, claims 1-3 and 6-8 are generic to any cell damaging agent. Claim 4 is generic to a cell damaging agent that is a virus vector for gene delivery. Claim 5 is generic to a cell damaging agent that is a virus vector for gene delivery encoding an immunomodulatory protein and/or a tumour antigen, or a functional fragment thereof. Claim 11 is generic to a cell damaging agent that is a herpesvirus vector for gene delivery. Claims 9-10 and 12 are specific to the elected invention (a cell damaging agent that is a herpesvirus encoding GM-CSF (9-10) or a herpesvirus vector encoding GM-CSF (12)).

Claims 1-7, 9, 11 and 12 are under consideration as they relate to a method of treating target cells to damage them and/or reduce their proliferation comprising a) exposing the target cells to a herpesvirus encoding GM-CSF, and b) exposing the target cells to antigen presenting cells (APCs), thereby to damage said cells and/or reduce their proliferation. Claims 8 and 10 are under consideration as they relate to treating cell proliferation in a subject comprising administering to said subject separately or concurrently a herpesvirus encoding GM-CSF and a preparation of APCs in combination with a pharmaceutical excipient.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on 6-6-00 (0013817.2). It is noted, however, that applicant has not filed a certified copy of the application as required by 35 U.S.C. 119(b).

Specification

3. The abstract of the disclosure is objected to because it contains legal language ("comprise") and because it does not reflect the elected invention (HSV encoding GM-CSF). Correction is required. See MPEP § 608.01(b).

Claim Objections

4. Claim 6 does not end in a period.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a tumor in a subject by a) directly administering a replication defective herpesvirus encoding GM-CSF into the tumor followed by b) directly administering dendritic cells syngeneic to the subject into the tumor, resulting in a decrease in growth or volume of the tumor, does not reasonably provide enablement for treating any target cells, using any APC, or delivering HSV-GM-CSF and APCs to target cells *in vitro* followed by implanting the target cells into a tumor in a subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed toward decreasing the proliferation or damage "target cells." The purpose of the method claimed is to treat hyperproliferating cells, e.g. tumor cells (pg 1, line 6; pg 2, line 23). The specification does not provide any other "target cell" or hyperproliferating cell other than tumor cells. Therefore, the claims should be limited to tumor cells to reflect the scope of the invention.

Claims 1-7, 9, 11 and 12 encompass "treating target cells" but are not limited to target cells in a subject or to treating tumors in a subject. The specification does not provide any enabled use for treating tumor cells that are not in a subject. Therefore, the claims should be limited to treating tumors in a subject.

Claims 8 and 10 are directed toward treating cell proliferation in a subject but are not limited to tumor cell proliferation and do not result in treating cell proliferation. The specification does not provide any enabled use merely administering the composition as claimed without treating cell proliferation. The specification does not provide an enable use for treating cell proliferation in any cell except a tumor cell. Therefore, the claims should be limited to treating tumor cell proliferation in a subject.

In general, the claims are directed toward using a herpes virus encoding GM-CSF to treat cell proliferation which falls into the realm of gene therapy.

The teachings in the specification suggest administering HSV-GM-CSF into a subject intratumorally followed by administering syngeneic dendritic cells (pg 13-16) but do not provide any results or correlate the results known in the art to those expected using HSV-GM-CSF followed by syngeneic dendritic cells. Thus, one of skill in the art would have been left to the art at the time of filing to determine the results.

While progress has been made in recent years for gene transfer *in vivo*, vector targeting to desired tissues *in vivo* continues to be unpredictable and inefficient as supported by numerous teachings available in the art. For example, Miller (1995, FASEB J., Vol. 9, pages 190-199)

review the types of vectors available for *in vivo* gene therapy, and conclude that "for the long-term success as well as the widespread applicability of human gene therapy, there will have to be advances...targeting strategies outlined in this review, which are currently only at the experimental level, will have to be translated into components of safe and highly efficient delivery systems" (page 198, column 1). Deonarain (1998, Expert Opin. Ther. Pat., Vol. 8, pages 53-69) indicate that one of the biggest problems hampering successful gene therapy is the "ability to target a gene to a significant population of cells and express it at adequate levels for a long enough period of time" (page 53, first paragraph). Deonarain reviews new techniques under experimentation in the art which show promise but states that such techniques are even less efficient than viral gene delivery (see page 65, first paragraph under Conclusion section). Verma (Sept. 1997, Nature, Vol. 389, pages 239-242) reviews vectors known in the art for use in gene therapy and discusses problems associated with each type of vector. The teachings of Verma indicate a resolution to vector targeting has not been achieved in the art (see entire article). Verma also teaches appropriate regulatory elements may improve expression, but it is unpredictable what tissues such regulatory elements target (page 240, sentence bridging columns 2 and 3). Crystal (1995, Science, Vol. 270, page 404-410) also reviews various vectors known in the art and indicates that "among the design hurdles for all vectors are the need to increase the efficiency of gene transfer, to increase target specificity and to enable the transferred gene to be regulated" (page 409).

However, in view of the unpredictability of gene therapy in general as cited above, HSV encoding GM-CSF was known to have a therapeutic effect under specific conditions.

Todryk (Nov. 20, 1999, Human Gene Therapy, Vol. 10, pg 2757-2769) taught injecting HSV-GM-CSF directly into tumors caused tumor reduction (pg 2762, col. 2, "direct *in vivo* delivery of DISC vectors," pg 2764, Fig. 4B). Todryk also taught injecting tumor cells infected with HSV-GM-CSF resulted in decreased tumor formation (pg 2762, col. 1, para. 1 through col. 2 para. 2). Todryk did not teach delivering APCs to the tumor cells; however, it is readily apparent to one of skill in the art that the tumor cells of Todryk are "exposed" to APCs as claimed because the tumors are within a mouse which has APCs. It is well known in the art that dendritic cells are found in tumors (see Ali (2002, pg 3512, col. 2, 6 lines from the bottom).

Ali (March 15, 2000, Cancer Res., Vol. 60, pg 1663-1670) taught administering irradiated tumor cells transfected with HSV encoding GM-CSF followed by challenge with non-irradiated, non-transfected tumor cells reduced the incidence and growth rates of tumors (pg 1666, col. 2, "Prophylactic..."). Ali also taught administering irradiated tumor cells transfected with HSV encoding GM-CSF next to established tumors reduced the incidence and growth rates of the established tumors (abstract, line 14; pg 1664, col. 1, last two para.; pg 1667, para. bridging col. 1-2).

Thus, given the art at the time of filing, one of skill would have been able to inject HSV-GM-CSF directly into a tumor and reduce tumor volume at the time of filing. In view of the general unpredictability of gene therapy taken with the teachings in the specification and the art at

the time of filing which taught one mode of delivery of HSV-GM-CSF that reduced tumor volume, one of skill would have been limited to that mode of delivery to reduced tumor volume.

Since the time of filing, it has been determined that injecting HSV-GM-CSF directly into a tumor followed by injecting syngeneic dendritic cells directly into the tumor reduced tumor volume.

Toda (Oct. 2000, Mol. Therapy, Vol. 2, pg 324-329) taught injecting HSV encoding GM-CSF directly into one of two tumors of a mouse reduced the volume of both tumors and increased survival of the mouse (pg 326, col. 2, "Treatment of established..."). Both tumors were found to contain prominent lymphocyte infiltration (pg 328, col. 1, line 5).

Ali (2002, J. Immunol., Vol. 179, pg 3512-3519) taught administering HSV encoding GM-CSF intratumorally followed by challenge with tumor cells at a distant body site inhibited tumor formation at the distant site (pg 3514, col.1, 4th full para.). Ali also taught administering HSV encoding GM-CSF intratumorally followed by administering syngeneic DC intratumorally resulted in decreased tumor growth (pg 3514, para. bridging col. 1 and 2; pg 3515, Fig. 2). It was determined that administering HSV-GM-CSF caused an increased CTL response against tumor antigen (pg 3515, col. 1, line 1). It is readily apparent to one of skill in the art that APCs are required to obtain the CTL response. Therefore, administering HSV encoding GM-CSF intratumorally inherently results in exposing tumor cells to APCs that result in a CTL response against the tumor.

Wong (2-10-01, Human Gene Therapy, Vol. 12, pg 253-265) taught administering HSV encoding GM-CSF directly into a tumor decreased the volume of the tumor and increased survival of the tumor (pg 257, col. 2, "subcutaneous flank tumor therapy"; pg 260, Fig. 4, Fig. 5A and 5B, NV1034).

Therefore, the specification also enables injecting HSV-GM-CSF directly into a tumor followed by injecting syngeneic dendritic cells directly into the tumor reduced tumor volume. It is noted that the claims are not limited to treating tumors, direct administration into tumors or syngeneic dendritic cells. The specification and the art at the time of filing does not teach any other APC besides dendritic cells that provides adequate antigen presentation to induce the desired effect. The specification does not teach how to use any APC that is not histocompatible with the subject. The specification does not teach any other mode of administering that will result in decreased tumors or correlate intratumoral injection to any other form of injection. Therefore, the claims should be limited to injecting HSV-GM-CSF directly into a tumor followed by injecting syngeneic dendritic cells directly into the tumor.

Claim 7 encompasses exposing target cells to the cell-damaging agent and APCs *in vitro* and implanting the target cells into a subject. Claim 8 encompasses administering HSV-GM-CSF and APCs "concurrently" to treat cell proliferation. The specification does not enable exposing a population of target cells HSV-GM-CSF *in vitro* followed by exposing the population of target cells to APCs *in vitro* or administering HSV-GM-CSF and APCs "concurrently. The specification suggests "the cell damaging agent can be delivered to target cells ex-vivo, this then be followed by

ex-vivo delivery to the treated target cells of an antigen-presenting cell preparation, e.g. dendritic cell preparation. It can be particularly useful to deliver the antigen-presenting cells, e.g. cells with substantial migratory activity, such as mature or pre-mature antigen-presenting cells, after an interval following exposures of target cells to the cell-damaging agent ex-vivo, which is as described above. The preparation comprising treated target cells and dendritic cells can then be administered to a subject of treatment such as a human, e.g. by direct injection." (pg 11, first para.). Overall, the paragraph is confusing. The phrase "...ex-vivo delivery to the treated target cells of an antigen-presenting cell preparation..." does not state the cells transfected with the virus *in vitro* are exposed to APCs *in vitro*. In fact, the phrase appears to mean dendritic cells are isolated from the host and introduced back into the tumor because the dendritic cells are used for "ex-vivo" delivery. It is not readily apparent that the phrase means the tumor cells transfected *in vitro* are exposed to APCs *in vitro* or that "treated target cells" are injected in the absence of APCs. While the last sentence of the paragraph contemplates injecting "treated target cells" and dendritic cells together, the specification does not teach the results of such a method. The specification does not correlate the results known in the art to reduce tumor (e.g. injecting HSV-GM-CSF followed by injecting dendritic cells) to those expected when HSV-GM-CSF-treated tumor cells and dendritic cells are injected together. It is unclear if the tumor cells are injected into existing tumors or if they are used to make tumors that grow more slowly. The specification does not provide adequate guidance for one of skill to use the claimed invention to treat tumors

when target cells are exposed to APCs *in vitro* or when HSV-GM-CSF and APCs are delivered "concurrently."

All of the HSV vectors described in the specification or known in the art are replication defective, i.e. they cause expression of the protein but do not cause viral infection. The specification does not teach any other HSV vector for use in gene therapy and it would require one of skill undue experimentation to determine how to make or use any other HSV vector for gene therapy that is not replication defective. Therefore, the claims should be limited to HSV vectors that are replication defective.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the metes and bounds of the steps claimed cannot be determined. The claim does not clearly set forth that herpes virus encoding GM-CSF is being administered to the "target cells", that the target cells are transfected with HSV-GM-CSF, or how the "target cells" are exposed to HSV-GM-CSF or the preparation of APC. It is unclear whether the virus is being injected into a host or into cells *in vitro*. The claim does not clearly set forth that the virus is transfecting the target cells. The claim does not clearly set forth that virus or

APCs are injected into an individual, which is the only disclosed purpose of the invention according to the specification (i.e. at least the APCs are injected into an individual). It is unclear if exposing "target cells" to a host having APCs is encompassed by exposing target cells to a preparation of APCs. It is unclear whether "said cells..." in the last line refers to target cells or antigen presenting cells. While the specification teaches injecting tumors with dendritic cells (pg 15, line 4), it is unclear if "exposing the target cells to a preparation of APCs" encompasses exposing target cells to APCs *in vitro* and/or exposing the target cells to APCs already in a host. It is unclear if the method encompasses administering APCs transfected with HSV-GM-CSF.

Claim 1 is indefinite because it is unclear how herpes virus encoding GM-CSF is a "cell-damaging agent." HSV-GM-CSF does not directly cause cell damage; the immune response to cells transfected with herpes virus encoding GM-CSF causes cell damage. Therefore, the virus does not damage cells.

Claim 2 is indefinite because it is unclear how step (b) occurs 30 minutes after step (a) if the APCs are already present in the host.

Claim 3 is indefinite because the metes and bounds of "consisting essentially of" cannot be determined. The specification does not define when a population of APCs are "essentially" dendritic cells or the "essential" function desired.

Claim 4 is indefinite because the metes and bounds of "consisting essentially of" cannot be determined. The specification does not define when a cell damaging agent is "essentially" a

herpes virus vector or the "essential" function of the virus. It is unclear if the virus must be a vector for DNA delivery or must damage cells.

Claim 6 is indefinite because it is unclear how the agent and APCs "delivered" in claim 6 correlate to the agent and APCs "exposed" in claim 1. It is unclear if claim 6 is limiting the "exposure" in claim 1 or if claim 6 is adding additional steps to claim 1.

Claim 7 is indefinite because the phrase "the treated target cells" lacks antecedent basis.

Claim 7 is indefinite because it is unclear how the agent and APCs "delivered" in claim 7 correlate to the agent and APCs "exposed" in claim 1. It is unclear if claim 7 is limiting the "exposure" in claim 1 or if claim 7 is adding additional steps to claim 1.

Claim 8 is indefinite because use of "separately or concurrently" in combination with the phrase "in combination with a pharmaceutical excipient" is unclear. It is unclear if the pharmaceutical excipient is required for administering the agent, the APCs or both. It is unclear if the claim encompasses administering the pharmaceutical excipient separately from the agent and the APCs.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. Claims 1-5 and 7-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Ali (March 15, 2000, Cancer Res., Vol. 60, pg 1663-1670).

Ali taught vaccination with irradiated tumor cells transfected with HSV encoding GM-CSF reduced the incidence and growth rates of tumors when administered adjacent to established tumors (abstract, line 14; pg 1664, col. 1, last two para.; pg 1667, para. bridging col. 1-2). The methods of Ali are equivalent to those in the specification. The tumor cells of Ali are the "target cells" claimed. The tumor of Ali is a "preparation of antigen presenting cells" as claimed because tumors have antigen presenting cells and because Ali taught the response was a CD8 T cell response which requires antigen presenting cells.

8. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Todryk (Nov. 20, 1999, Human Gene Therapy, Vol. 10, pg 2757-2768).

Todryk taught injecting a mouse with tumor cells transfected with HSV encoding GM-CSF reduced the formation of tumors. Todryk also directly injected HSV encoding GM-CSF into tumors which resulted in reduction of tumors (abstract, line 9; pg 2758, col. 2, last 6 lines; pg

2762, para. bridging col. 1-2). The methods of Todryk are equivalent to those in the specification. The tumor cells of Todryk are the "target cells" claimed. Injecting the transfected tumor cells into a mouse as taught by Todryk is equivalent to exposing tumor cells to a "preparation of antigen presenting cells" as claimed because mice contain antigen presenting cells.

9. Claims 1, 3-5, 9, 11 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Boursnell et al. (US 6,344,445, Feb. 5, 2002).

Boursnell taught exposing tumor cells to HSV-GM-CSF and exposing the transfected tumor cells with leukocytes *in vitro* (col. 6, line 41). Leukocytes inherently contain dendritic cells and dendritic cells are a type of leukocyte. Claim 3 is included because the metes and bounds of "consisting essentially of" is unclear (see 112/2nd).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sin (1998, Euro. J. Immunol., Vol. 28, pg 3530-3540) which taught administering GM-CSF cDNA as a vaccine adjuvant for HSV-2.

Wei (1995, Proceedings of the American Assoc. for Cancer Research Annual Meeting, Vol. 36, pg 424) which taught a retroviral vector encoding HSV-TK and GM-CSF.

Yang (1995, J. Cell. Biochem. Supp., Vol. 0, No. 21A, pg 429) which taught a retroviral vector encoding HSV-TK and GM-CSF.

Molnar-Kimber (US 6,428,968, Aug. 6, 2002) which teaches administering HSV-GM-CSF in combination with a chemotherapeutic agent (claim 1, col. 9, line 58).

Boursnell et al. (US 6,287,557, Sep 11, 2001) which taught administering HSV-GM-CSF intratumorally reduced tumors.

Fong et al. (US 6,051,428, April 18, 2000) which taught administering HSV-GM-CSF intratumorally reduced tumors.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER